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| 10/773,079 | 02/05/2004 | William Jackson Devlin SR. | DCS-9119B | 6037 |

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| EXAMINER | |
|---|---|
| GAKH, YELENA G | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/773,079 | DEVLIN ET AL. | |
| | Examiner | Art Unit | |
| | Yelena G. Gakh, Ph.D. | 1797 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. Amendment to the specification and claims filed on 12/26/07 is acknowledged. Claims 1-10 are pending in the application.

### *Response to Amendment*

2. The amendment filed 12/26/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: claim 3 recites that the tests to be performed are used to determine the period of storage time, which is represented in the bar code. The examiner failed to find corresponding disclosure in the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

3. In response to the amendment the examiner withdraws objection to the specification and drawings and rejection of the pending claims under 112, first paragraph. Rejection of the pending claims under 112, second paragraph, is modified in light of the amendment. The rejection of the pending claims over the prior art is sustained; new rejection over the prior art is added in light of the amendment.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "providing bar code indicia on the original sample container to indicate a predetermined period of storage time". It is not apparent, as to how the period of storage time is related to the test to be performed with the first aliquot of the sample, recited in the preamble of the claim. Is it the storage time related to expiration date of the sample? Is it some other predetermined storage time?

Claim 3 recites "tests to be performed are used to determine the period of storage time". It is not quite clear, what this means. Does it mean that the time period for performing the tests is the storage time? Or it is a different time? How do the tests define the time?

Claim 8 is unclear for the same reasons. It is not apparent, as to what is "using the identity of said tests to determine a storage period of time for said second aliquot portion". What is "identity of the tests", and how this identity can be used to define the storage period of time for the sample?

Claims 9 and 10 recite the limitation "the indicia on the sample container", which does not have an antecedent basis for the amended claims.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1-3, 5 and 7-9** are rejected under 35 U.S.C. 102(b) as being anticipated by Young et al. (US 3,565,582) (Young).

Young teaches "methods and means for handling blood test specimens", with the method comprising the following steps:

> "some of the serum is transferred from the initial or first vessel to the other or second vessel. A sample of the specimen is withdrawn and is subjected to the test sequence which includes the testing and presentation of the test result. These steps, withdrawal of the sample, testing and presentation of test results are accomplished according to a predefined time schedule. An added step in the process, and one which may be accomplished at any point in the process this far described, is to apply to the container indicia or data which will identify the specimen and the test to which it is to be subjected" (col. 3, lines 60-72). "*Upon withdrawal of a test sample a specimen upon which other tests are to be run is placed in storage and is then submitted to another timed sequence of steps including sample withdrawal, testing and presentation of test results. The storage step may be included in the time sequence of the steps. The step of reading the data in the container and correlating that data with test results will also be included in the timed sequence of steps*" (col. 4, lines 10-16).

The method also comprises providing:

> "a double vessel container for blood and its serum, which is capable of bearing data identifying the blood and the test prescribed together with apparatus for reading that data and for conducting tests according to a predetermined relative time schedule" (col. 3, lines 48-53).

> "It is implicit in the preceding discussion that the several steps in the method may be separated by storage steps in which specimens are stored in the double vessel container. Any storage prior to application of identification data to the container must be controlled to prevent loss of identity. In addition, in the interval between removal of the sample and correlation of identification data and test result there must be a control to enable proper correlation which involves accomplishment of any storage steps on a timed basis for integral multiples of the unit time period employed in the process" (col. 8, lines 10-20) (which depends on the test to be performed, see col. 7).

> "A cover 44 is provided for the container to insure cleanliness prior to use and to insure that the blood and serum are not contaminated with dirt and other foreign matter once they are placed in the container" (col. 6, lines 19-22).

Yong discloses a method performed on the apparatus, which is a predecessor of convention modern automatic analyzers, well known in the prior art, and thus the container indicia with "data applicator" is analogous to conventional modern bar code indicia. The examiner believes that the disclosure in terms, which were conventional for the state of the prior art in the time of Young's invention, covers the subject matter of the indicated claims.

### *Claim Rejections - 35 USC § 103*

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. **Claims 4, 6 and 10** are rejected under 35 U.S.C. 102(b) as being anticipated by Young et al. (US 3,565,582) (Young).

While Young does not specifically disclose an aliquot strip having a number of open aliquot wells (claim 4), and disposing the sample or displaying an alert signal after the storage time expires, using aliquot strips is conventional of automated analysis of biological samples in the art; regarding claims 6 and 10 Young teaches: "it is to be noted, and it is a feature of the invention, that the method imposes no limitation on the time during which tests must be conducted except for that the maximum time for conducting tests must be known". It would have been obvious for a person of ordinary skill in the art to set an alert system and dispose the sample which storage time exceeded the maximum time for analysis.

10. **Claims 1-4, 6 and 9-10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazza (US 5,350,564, IDS) in view of Thorne et al. (US 4,678,752, IDS).

Mazza discloses, "the present invention relates to an adaptive, versatile conveyor system for feeding individual sample tubes, cells, *cuvettes*, and the like (hereinafter collectively referred to as "sample tubes") each held in an individual prismatic sample tube carrier, either from associated groups or batches which are taken in regular order, or from a stat sample area taken with priority; identifying the individual sample tubes; conveying and/or temporarily storing the individual sample tubes as required; transferring the individual sample tubes to and from one or more associated analysis modules of the apparatus as appropriate; ***retaining the individual sample tubes in temporary storage while test results are obtained, and returning the individual sample tubes to associated groups in response to an indication that analysis of a particular sample is complete and verified as reliable***. The present invention has particular utility for use in automated chemical analyzers and related equipment for analysis and testing of blood, physiological fluids, and other biological samples" (col. 1, lines 18-38); "the carriers are individually fed to a rotator assembly which provides both for the *reading of a bar code tag on the sample tube* in the carrier, and the rotational orientation of the carrier in a particular presentation" (col. 5, lines 20-24). Sample carriers returned from an analyzer to the loop conveyor are retained thereon, along with incoming samples en route to an analyzer, and priority stat samples which will be received by an analyzer prior to the rank and file samples, until the results of the tests on the sample are confirmed. Thus, the loop conveyor provides a dwell capacity in association with the analyzer. This dwell capacity also allows rank and file samples to be held in abeyance on the loop conveyor while stat samples traverse the conveyor immediately en route to the analyzer. *In the event the test results are not confirmed, the particular sample may be fed from the loop conveyor back to the analyzer for a second or subsequent testing*" (col. 5, lines 33-43).

"The entire operation of the conveyor is under the control of a dynamic controller so that each discreet action with respect to a sample carrier from the time its sample is identified until the sample test results are verified and the carrier is off loaded is tracked. Thus, test results are easily correlated with a particular sample and patient. Also, the location of each sample on the loop conveyor, and of vacant receptacles, which are available for receipt of a stat or of a rank and

file sample, is always recorded. *This feature of the conveyor along with its storage and dwell time feature makes possible the recall to an analyzer module of any particular sample in the event the results of a test are not verified as reliable.* This latter feature is of high importance with stat samples. If the test results for any start sample are not reliable, the sample will be recalled to the analyzer and retested. Only when the test results of each sample are verified will the sample be delivered to the off-loading area" (col. 5, lines 56-68, col. 6, lines 1-6).

Mazza does not specifically indicate that the bar code on the sample container has information on the time period for the sample to be retained at the storage compartment.

Thorne discloses an automatic random access analyzer comprising an environmentally controlled (col. 10, lines 60-67) incubation storage area 18 within the analyzer for storing a plurality of reagent packages comprising reagent solutions, with the packages having barcode labels 46 with the information on expiration date (col. 5, lines 60-68). The reagents are automatically extracted for further use in automated analyzer.

It would have been obvious for any person of ordinary skill in the art to slightly modify Mazza's method by including information on the time period during which the sample can be retained in the storage space for further analysis the way it is taught by Thorne for the reagents, either because the samples can degenerate with time the same way the reagents do and become unacceptable for further analysis, or because the samples should be stored only for the time period when they might be required for re-testing, as indicated by Mazza. Therefore, it would have been obvious for any person of ordinary skill in the art to discard the samples which were retained in the storage compartment for the period of time exceeding the expiration date (the time period) and to alert the user about such expiration of the time period.

11. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazza in view of Thorne, as applied to claims 1-4, 6 and 9-10 above, and further in view of the well known prior art, e.g. Boosalis et al. (US 4,362,698, IDS).

Although Mazza in view of Thorne do not specifically indicate using a protective film (layer, lid, foil, etc.), which can be easily removed or pierced, their use for covering the samples to be analyzed are well known in the art, as disclosed by e.g. Boosalis.

While Boosalis discloses a more complex cover for fluid sample cups, which serves many purposes and contains several layers, including film, adhesive tape, etc., it would have

been obvious for anyone of ordinary skill in the art to use any simple cover for sample in Mazza's method, including film, foil, plastic, etc., which is just one layer of Boosalis' cover and which may serve exclusively for protection of the samples and, on the other hand, be easily removed or pierced, because it is a conventional way of protecting samples of biological analytes from contamination during analysis.

***Response to Arguments***

12. Applicant's arguments filed 12/26/07 have been fully considered but they are not persuasive. Since examiner withdraws rejection of the claims under 112, first paragraph, the Applicants' arguments regarding this rejection are moot. New rejection under 112, second paragraph, is established.

Regarding rejection of the pending claims over the prior art, the examiner does not quite understand the Applicants statement: "it is noted that Mazza's conveyor only temporarily stores a sample until such time as valid test results are reported. There is no disclosure of a key feature of applicants inventive concept of storing a sample aliquot for a predetermined period of time based on the identity of either the original sample or of the tests to be conducted on the sample". The paragraphs cited by the Applicants as forming the basis for the claimed subject matter, i.e. [0036] "[i]ncoming specimens to be tested are identified by reading with a bar code reader 49 bar coded indicia on sample tubes 14 to determine, among other items, a patient's identity, the tests to be performed, if a sample aliquot is desired to be retained and if so, for what period of time" and [0046] "[i]ncoming specimens to be tested are identified by reading with a bar code reader 49 bar coded indicia on sample tubes 14 to determine, among other items, a patient's identity, the tests to be performed, if a sample aliquot is desired to be retained and if so, for what period of time" say nothing about the period of time based on the identity of the tests to be conducted on the sample. As for the sample to be re-called and re-tested disclosed by Mazza, there is no doubt that Mazza is teaching the same sample that should be re-tested, and not any other sample. It is clearly demonstrated by the following excerpts: *"in the event the test results are not confirmed, the particular sample may be fed from the loop conveyor back to the analyzer for a second or subsequent testing"*; and *"this feature of the conveyor along with its storage and dwell time feature makes possible the recall to an analyzer module of any particular sample in the event the*

*results of a test are not verified as reliable"* (see above). It is not apparent, as to how it would be possible to conclude that Mazza means different samples.

The only difference between Mazza's disclosure and the instant application is that Mazza does not specifically teach indicating the time period for storing the sample in bar code indicia. Thorne discloses bar codes which indicate the time period for expiration of the reagents. While the examiner indicated that pre-determined time period for storing the samples can be also the expiration period, the motivation for applying Thorne's teaching in Mazza's method follows directly from Mazza's disclosure. In fact, Mazza teaches that the samples should be stored in the environmentally controlled place only for the time period, when the first aliquots are tested and the test results are analyzed to find out whether the tests should be repeated. Therefore, the motivation for indication of pre-determined time in bar code follows from Mazza's disclosure. Moreover, the examiner respectfully disagrees with the Applicants regarding their statement that there is no motivation to indicate when the sample should be discarded, which may be related to its degradation. In fact, the pre-determined time could be well defined by the possible degradation of the biological samples. It is not quite clear, whether the Applicants state that biological samples can be stored for infinite period of time under conditions, which could provide fast access of the samples for testing (i.e. avoiding deep freezing), with biological samples being non-degradable. In any case, no matter, which specific time period for storing the sample in environmentally controlled condition for re-testing the sample is defined, the motivation to have this time period pre-determined and conveniently stored in the bar code indicia is fully provided by the combination of Mazza and Thorne.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yelena G. Gakh/
Primary Examiner, Art Unit 1797

2/28/2008